

Amendment

In the Claims

1-22. Canceled

23. (currently amended) A method of making a milnacipran formulation comprising providing ~~the formulation of claim 1~~ a milnacipran formulation that provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects.

24. (currently amended) A method for delivering a therapeutic dose of milnacipran to a patient in need thereof, with diminished incidence or reduced intensity of common milnacipran side effects, comprising administering to the patient in need thereof ~~the milnacipran formulation of claim 1~~ a milnacipran formulation that provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects.

25. (new) The method according to Claim 24, wherein the side effect is nausea.

26. (new) The method according to Claim 24, wherein the side effects are selected from the group consisting of vomiting, headache, tremulousness, anxiety, panic attacks, palpitations, urinary retention, orthostatic hypotension, diaphoresis, chest pain, rash, weight gain, back pain, constipation, vertigo, increased sweating, agitation, hot flushes, tremors, fatigue,

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somnolence, dyspepsia, dysoria, nervousness, dry mouth, abdominal pain, irritability, and insomnia.

27. (new) The method according to Claim 24, wherein the formulation has a milnacipran release profile that is characterized by release of less than approximately 10% of the total dose over a period up to four hours, followed by a slow or extended drug release.

28. (new) The method according to Claim 27, wherein the defined period of time is between approximately four and approximately twenty-four hours.

29. (new) The method according to Claim 24, wherein the formulation provides milnacipran blood plasma levels that are characterized by T_{\max} at 4-10 hours, and C_{\max} below approximately 3000 ng/ml.

30. (new) The method according to Claim 29, wherein the formulation provides milnacipran blood plasma levels that are characterized by C_{\max} below approximately 2000 ng/ml.

31. (new) The method according to Claim 24, wherein the formulation provides milnacipran blood plasma levels that are characterized by C_{\max} below approximately 1000 ng/ml.

32. (new) The method according to Claim 24, wherein the formulation further comprises at least one other active compound selected from the group consisting of analgesics, anti-inflammatory drugs, antipyretics, antidepressants, antiepileptics, antihistamines, antimigraine drugs, antimuscarinics, anxiolytics, sedatives, hypnotics, antipsychotics,

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bronchodilators, anti asthma drugs, cardiovascular drugs, corticosteroids, dopaminergics, electrolytes, gastro-intestinal drugs, muscle relaxants, nutritional agents, vitamins, parasympathomimetics, stimulants, anorectics, and anti-narcotics.

33. (new) The method according to Claim 32, wherein the formulation comprises compounds selected from the group consisting of aceclofenac, acetaminophen, adomexetine, almotriptan, alprazolam, amantadine, amcinonide, aminocyclopropane, amitriptyline, amolodipine, amoxapine, amphetamine, aripiprazole, aspirin, atomoxetine, azasetron, azatadine, beclomethasone, benactyzine, benoxaprofen, bermoprofen, betamethasone, bicifadine, bromocriptine, budesonide, buprenorphine, bupropion, buspirone, butorphanol, butriptyline, caffeine, carbamazepine, carbidopa, carisoprodol, celecoxib, chlordiazepoxide, chlorpromazine, choline salicylate, citalopram, clomipramine, clonazepam, clonidine, clonitazene, clorazepate, clotiazepam, cloxazolam, clozapine, codeine, corticosterone, cortisone, cyclobenzaprine, cyproheptadine, demexiptiline, desipramine, desomorphine, dexamethasone, dextranabinol, dextroamphetamine sulfate, dextromoramide, dextropropoxyphene, dezocine, diazepam, dibenzepin, diclofenac sodium, diflunisal, dihydrocodeine, dihydroergotamine, dihydromorphine, dimetacrine, divalproxex, dizatriptan, dolasetron, donepezil, dothiepin, doxepin, duloxetine, ergotamine, escitalopram, estazolam, ethosuximide, etodolac, femoxetine, fenamates, fenoprofen, fentanyl, fludiazepam, fluoxetine, fluphenazine, flurazepam, flurbiprofen, flutazolam, fluvoxamine, frovatriptan, gabapentin, galantamine, gepirone, ginkgo bilboa, granisetron, haloperidol, huperzine A, hydrocodone, hydrocortisone, hydromorphone,

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hydroxyzine, ibuprofen, imipramine, indiplon, indomethacin, indoprofen, iprindole, ipsapirone, ketaserin, ketoprofen, ketorolac, lesopitron, levodopa, lipase, lofepramine, lorazepam, loxapine, maprotiline, mazindol, mefenamic acid, melatonin, melitracen, memantine, meperidine, meprobamate, mesalamine, metapramine, metaxalone, methadone, methadone, methamphetamine, methocarbamol, methylidopa, methylphenidate, methylsalicylate, methysergid(c), metoclopramide, mianserin, mifepristone, milnacipran, minaprine, mirtazapine, moclobemide, modafinil, molindone, morphine, morphine hydrochloride, nabumetone, nadolol, naproxen, naratriptan, nefazodone, neurontin, nomifensine, nortriptyline, olanzapine, olsalazine, ondansetron, opipramol, orphenadrine, oxaflozane, oxaprazin, oxazepam, oxitriptan, oxycodone, oxymorphone, pancrelipase, parecoxib, paroxetine, pemoline, pentazocine, pepsin, perphenazine, phenacetin, phendimetrazine, phenmetrazine, phenylbutazone, phenytoin, phosphatidylserine, pimizide, pirlindole, piroxicam, pizotifen, pizotyline, pramipexole, prednisolone, prednisone, pregabalin, propanolol, propizepine, propoxyphene, protriptyline, quazepam, quinupramine, reboxitine, reserpine, risperidone, ritanserin, rivastigmine, rizatriptan, rofecoxib, ropinirole, rotigotine, salsalate, sertraline, sibutramine, sildenafil, sulfasalazine, sulindac, sumatriptan, tacrine, temazepam, tetrabenazine, thiazides, thioridazine, thiothixene, tiapride, tiasipirone, tizanidine, tofenacin, tolmetin, toloxatone, topiramate, tramadol, trazodone, triazolam, trifluoperazine, trimethobenzamide, trimipramine, tropisetron, valdecoxib, valproic acid, venlafaxine, viloxazine, vitamin E, zimeldine, ziprasidone, zolmitriptan, zolpidem, zopiclone and isomers, salts, and combinations thereof.

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34. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of dextrogyral or levogyral enantiomers of the milnacipran or pharmaceutically acceptable salts thereof.

35. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of a mixture of milnacipran enantiomers or pharmaceutically acceptable salts thereof.

36. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of the active metabolite of milnacipran or pharmaceutically acceptable salts thereof.

37. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of para-hydroxy-milnacipran (F2782) or pharmaceutically acceptable salts thereof.

38. (new) The method according to Claim 24, wherein the formulation further comprises an enteric coating.

39. (new) The method according to Claim 24, wherein the formulation comprises a milnacipran dose from 25 to 500 mg.

40. (new) The method according to Claim 24, wherein the formulation comprises a milnacipran dose from 200 to 500 mg.

41. (new) The method according to Claim 40, wherein the formulation comprises 25 to 500 mg milnacipran and 100 to 600 mg modafinil.